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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/068,751      | 11/02/1998  | WOLFGANG-M. FRANZ    | 690-110PCT          | 2640             |

2292 7590 12/20/2001

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EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/068,751

Applicant(s)

FRANZ ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 52-73 and 76-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-73 and 76-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The request filed on 09/28/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/068,751 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 52-73 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement in view of the Amendment received 12/4/01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

4. Claims 52-73 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific Ad-rsvLuc compositions exemplified in the specification, i.e. particular viral vectors having the significant regions of the adeno-viral vector and the mlc-2 promoter as to achieve the unexpected results over the prior art (such as the disclosed Buttrick et al. paper argued in the response received 12/4) and methods of administering such compounds via direct injection to the cardiac tissue discussed by Franz et al. (Cir. Res. 73 (4), p. 629-38), does not reasonably provide enablement for the scope of any viral containing mlc-2 composition claimed nor for expression via any route of administration as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Applicant's arguments filed 5/18/00, 12/28/00 and in the new amendment received 12/4/01 have been fully considered but they are not persuasive.

In the Interview with Applicant on 11/16/01, unexpected results were discussed with respect to the previous 35 U.S.C. 103 rejection. Specifically, it was pointed out that it was the combination of the adenoviral vector used and the specific regions of the *mlc-2* promoter which produced the successful cardiac-specific tissue expression of the disclosed constructs *in vivo*. Applicant reiterates this argument in the Amendment received 12/4/01 and an accompanying declaration which points out in section 5 (pages 2-3 of the declaration) the unpredictability of the combination of *mlc* promoters and viral vectors for cardiac-specific tissue expression in a somatic gene transfer *in vivo*. The 35 U.S.C. 103 rejection was removed in view of the unpredictability in the art for use of such viral vectors under conditions of somatic gene transfer as instantly claimed.

However, several unpredictable issues remain with regard to the scope of the instant claims. In the face of the unpredictability in the art taught (1) in the Franz et al. (Card Res. 35 (1997), pages 564-565 especially) for expression of any muscle specific tissue specific expression *in vivo*, (2) in the abstracts disclosed in the Amendment received 12/4/01 for cardiac-specific tissue expression by other cardiac promoters, and (3) the general unpredictability in the field of somatic gene transfer *in vivo* for design of functional vectors as taught by Anderson (argued previously) and by Reynolds et al. (Molecular Medicine Today, 1/99, pages 25-30), one skilled in the art would still not be enabled to make and use the scope of viral vectors claimed and by any

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route of administration claimed (since claim 69 was amended to remove the limitation that delivery is by direct injection in to the cardiac muscle). It is not clear from the specification as filed nor the references cited which regions of the Ad-mlc-Luc construct in combination with which portions of the mlc-2 construct were responsible for the success in tissue specific cardiac expression by these constructs. Nor is it clear what viral vectors would provide for the results obtained for cardiac-specific tissue expression *in vivo*. Thus, in view of the unpredictability in the art for gene therapy with any viral construct and the unpredictability in the art for cardiac specific expression of mlc promoters from viral vectors argued by Applicant, one skilled in the art would necessarily need to practice "trial and error" experimentation to make and use the invention scope claimed. Furthermore, in view of the unpredictability in the art argued previously for gene therapy constructs with respect to delivery, formulation, stability and sustained expression *in vivo*, one skilled in the art would necessarily practice "trial and error" experimentation to administer the claimed constructs via any route of administration. Without specific guidance in the art and/or from the specification as filed as to how to make and use the broad scope of viral vectors and methods of use claimed by any route of administration, one skilled in the art would necessarily practice an undue amount of experimentation to make and use the claimed invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.



JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
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M. M. Schmidt  
December 10, 2001